|  |
| --- |
| **GENERAL INSTRUCTIONS** – delete this box from the submitted consent formThis template is for research involving adults. Do not use this template for research involving children; instead use “Assent Template” if children are subjects. Use this template as follows: * Red text represents instructions to you – to be deleted from the final version. For example, when a section starts with “[Include if…],” you should read the red bracketed phrase, and either delete the whole section if not applicable to your study or delete just the red bracketed phrase and retain the section if applicable to your study.
* Blue text represents guidance on suggested content – to be edited and changed to black or replaced with black in the final version. The language should be understandable at an 8th grade reading level.
* Black text represents text that should ordinarily be incorporated as-is, if applicable

If your study involves any of the following, see the specific instruction box at the end of this template:* Genetic testing and/or collecting genetic information
* Communication of pertinent and/or incidental findings to subjects and/or their physicians
* Repositories or other retention of samples or data
* ICH-GCP

There are five signature pages at the end of this template; use the one that is applicable and delete the remaining four. Please note that you must enter the project title and PI name in black in the header on the second page. The submitted version should have no red or blue text (including instruction boxes like this one) |

Use this header:

**Texas A&M University-Kingsville**

**IRB Informed Consent Form, IRB # \_\_\_\_\_\_\_\_\_\_**

**CONSENT FOR RESEARCH PARTICIPATION**

Title of Project: Title

[Include if there is one or more external sponsor; otherwise, delete paragraph] Sponsor: External sponsor(s).

Principal Investigator:

|  |  |
| --- | --- |
| PI Name: | Type here |
| PI contact phone: | Type here |
| PI contact email: | Type here |

Co-Investigator(s): Delete section if no Co-PI, copy/paste if more than one

|  |  |
| --- | --- |
| Co-PI Name: | Type here |
| PI contact phone: | Type here |
| PI contact email: | Type here |

Student-Investigator: Delete section if no SI, copy/paste if more than one

|  |  |
| --- | --- |
| SI Name: | Type here |
| SI contact phone: | Type here |
| SI contact email: | Type here |

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when deciding whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

|  |
| --- |
| **Key Information for You to Consider** |
| * **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
* **Purpose**. The purpose of this research is [provide a brief description of why the research is being conducted, no more than 2-3 sentences].
* **Duration.** It is expected that your participation will last [expected duration].
* **Procedures and Activities.** You will be asked to [briefly highlight the key research activities/procedures].
* **Risks.** Some of the foreseeable risks or discomforts of your participation include [describe the most important risks. Consider those most probable and/or highest magnitude of harm].
* **Benefits**. Some of the benefits that may be expected include [insert direct benefits, or if no direct benefit to subject state no direct benefit but the researchers hope to learn/gain xyz].
* **Alternatives.** As an alternative to participation, you could [note appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. If there are no alternatives, state that, “Participation is voluntary, and the only alternative is to not participate.”].
 |

**Why is this research being done?**

A brief explanation of the purpose of the study, stating in lay language what the study is designed to discover or establish. Do NOT copy from a grant application or other scientific description.

**What Will Happen in This Research Study**

A concise description of study procedures in enough detail to give a clear picture of what the subject will experience during the study. Explain the overall design of the study and describe procedures to be followed (including pregnancy testing if applicable), the location and length of time for the procedures, the frequency of procedures, and as appropriate, such study details as how subjects will be assigned to study groups, the method, dose, and frequency of medication administration, and specific tasks subjects will be expected to complete on their own. Any experimental procedures must be identified as such and differentiated from standard treatments. Technical language unfamiliar to the subject population should not be used. Subheadings may be inserted to make this section more readable.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

[Include if subjects will be audio- or video-recorded at any point in the research and this is NOT reviewable through limited review; otherwise, omit sentence] We will make an audio OR a video recording of specify what will be recorded. [include only if the study is more than minimum risk] Do you grant permission for us to make an audio and/or a video recording of you? **If this is an exempt study you still need to state the participants they will either be audio or video recorded but they do not need to check the boxes or initial. You will want to remove the check boxes and initials.**

 YES NO Initial \_\_\_\_\_\_\_

[Include if the approximate total number of subjects in the entire study would be relevant to the decision about whether or not to participate; for example, if the number of participants is small so that unknown risks are less likely to be identified and/or deductive identification of their participation is more likely; otherwise, delete sentence] You will be one of approximately number subjects who will be asked to be in the study.

**Risks and Discomforts**

A description of all reasonably foreseeable risks and discomforts, their likelihood of occurrence (when appropriate), and the steps you will take to minimize these risks. Include psychological, social, legal, and financial as well as physical risks. If applicable, identify any situations where the subject should seek immediate medical care. Do NOT include the risk of loss of confidentiality to avoid duplicating information in the **Confidentiality** section.

[Include if the study is greater than minimal risk; otherwise, delete sentence] There may be unknown risks or discomforts involved.

[Include if there are any consequences of a decision to withdraw from the study or any necessary procedures for withdrawing; otherwise, delete paragraph] If you decide that you want to stop being in the study, we ask that you let us know. If you stop early, list the risks of withdrawing. You are free to stop at any time, but if you tell us, we can do some things to help keep you safe. These things include list procedures for orderly withdrawal.

[Include and edit if women in the study should not become pregnant because of risks to the fetus; otherwise, delete paragraph] If you get pregnant while you are in this study, it could be bad for the fetus/baby. You must use birth control if you are a woman having sex with men while you are in this study. [Include or modify time frame if applicable; otherwise, delete] You should also keep using birth control for three months after the study ends. Only some birth control methods work well enough to be safe while you are in this study. These methods are oral contraceptives (the pill), intrauterine devices (IUDs), contraceptive implants under the skin, contraceptive rings or patches or injections, diaphragms with spermicide, and condoms with foam. You should not be in this study if you are a woman who has sex with men and cannot use one of these birth control methods; or if you are a woman currently undergoing In Vitro Fertilization (IVF) fertility treatment.

**Potential Benefits**

[Include A or B]

[A. Include if there is a potential direct benefit to subjects; otherwise, delete paragraph] The benefits of being in this study may be: list potential benefits. However, you may not receive any benefit. Your being in the study may help the investigators learn list what investigators may learn.

[B. Include if there is no potential direct benefit to subjects; otherwise, delete paragraph] You will receive no direct benefit from being in this study. Your being in this study may help the investigators learn list what investigators will learn.

[Include **Alternatives** if the study is expected to have a direct benefit; otherwise, delete **entire** Alternatives section]

**Alternatives**

The following alternative procedures or treatments are available if you choose not to be in this study: list of alternatives, including other methods to get potential direct benefits or palliative care if appropriate.

**Costs**

[Include A, B, or C]

[A. Include and edit this entire paragraph if the study uses any clinical services (include the first sentence if the study uses a clinical intervention, drug, or device); otherwise, delete paragraph] The study intervention/drug/device will be provided through the study. There are no OR some additional costs to you for being in the study. [Include if there are additional costs; otherwise, delete] The additional costs are (describe). Items and services done only for study purposes will be provided at no cost to you. They won’t be billed to your health insurance either.

[B. Include if the study does not cover the cost of clinical services and subjects may incur any costs; otherwise, delete sentence] If you are in this study, you will have to pay for list costs

[C. Include if the subjects will not incur any costs; otherwise, delete sentence] There are no costs to you for being in this research study.

**Compensation**

[Include A or B; include C if applicable]

[A. Include if subjects will be given any payment or reimbursement; otherwise, delete paragraph] You will receive description of amount, method, and timing, including how payment will be prorated if the subject withdraws.

[B. Include if subjects will not receive any payment or reimbursement; otherwise, delete paragraph] You will not be paid for being in this study.

[C. Include if the research could lead to commercial products; otherwise, delete paragraph] The research may lead to the development of drugs, tests, or procedures that might have commercial value. You will not get any money if products are developed from the research.

**Confidentiality**

[Include A or B]

[A. Include the following paragraph and delete the remainder of the Confidentiality section if study does NOT record ANY information that would identify subjects; otherwise, delete paragraph] We will not record your name or any information that shows your identity. You will not be signing this form. Further explanation of measures to preserve anonymity, if appropriate.

[B. Include the following paragraph and the remainder of the Confidentiality section if study does record ANY information that would identify subjects; otherwise, delete paragraph] We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. [Include next sentence if biospecimens are collected; otherwise, delete sentence] We will store biological samples taken from your body (such as urine, blood, or tissue) describe storage methods. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.

If you agree to be in the study and sign this form, we will share information and biological samples that may show your identity with the following groups of people:

* People who do the research or help oversee the research, including safety monitoring.
* People from Federal and state agencies audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, and the National Institutes of Health.
* [Include and edit if identifiable study information or samples will be released to anyone not included in the above bullets (for example, investigators not included in the research team for this study); otherwise, delete bullet] People who will get information and biological samples from us describe who will get the information and why. These people are expected to protect your information and biological samples in the same way we protect it.
* Any people whom you give us separate permission to share your information.

[Include and edit if study gathers information that requires mandatory reporting (this applies to studies where the information is intentionally collected and to studies conducted by mandated reporters in a setting where abuse or neglect is directly observable, such as a home, school, daycare, or nursing home); otherwise, delete bullet] You should know that we are required to report information about list information such as child abuse or neglect; elder abuse; specific reportable diseases; harm to self or others.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

* Publishing results in a professional book or journal.
* Adding results to a Federal government database.
* Using research data in future studies, done by us or by other scientists.
* [Include if biospecimens are collected; otherwise, delete bullet] Using biological samples in future studies, done by us or by other scientists.

[Include and edit if the study involves focus groups; otherwise, delete paragraph] We will ask everyone in the focus group not to talk about the discussions outside the group. However, we can’t promise that everyone will keep what you say confidential.

[Include without editing if the study is a clinical trial that is sponsored by NIH or includes a drug, biologic, or device (note – observational studies that monitor drug treatment but do not involve interventions are not clinical trials); otherwise, delete paragraph] A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

[Include **Compensation for Injury** if the study is greater than minimal risk; otherwise delete **entire** Compensation for Injury section] **Compensation for Injury**

If you think that you have been injured by being in this study, please let the investigator know right away. Use the phone number on the first page of this form. There is no program to provide compensation for the cost of care for research-related injuries or other expenses. Other expenses might be lost wages, disability, pain, or discomfort. You or your insurance will be billed for the medical care you receive for a research injury. You are not giving up any of your legal rights by signing this form.

[Include **Re-Contact** if you might re-contact the subjects after the study is over (delete any categories that are not applicable to your study); otherwise, delete **entire** Re-Contact section. If this study is EXEMPT, delete **entire** Re-Contact section.] **Re-Contact**

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

 \_\_\_\_Yes \_\_\_\_No You may contact me again to ask for additional information related to this study

 \_\_\_\_Yes \_\_\_\_No You may contact me again to ask for additional biological samples related to this study

 \_\_\_\_Yes \_\_\_\_No You may contact me again to let me know about a different research study

 \_\_\_\_Yes \_\_\_\_No You may contact me again to list reason – or delete line

**Potential Conflict of Interest:**

 [Include if the PI or any study investigator could also be the subject’s healthcare provider; otherwise, delete paragraph] Your healthcare provider may also be an investigator in this research study. Being an investigator means your healthcare provider is interested in both you and the study. You may want to get a second opinion about being in the study. You can do so now or at any time during the study. Another healthcare provider who is not an investigator can give you a second opinion about being in the study. You do not have to agree to be in this study even though it is offered by your healthcare provider.

**Subject’s Rights**

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study, you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you.

[Include if the study is healthcare dependent; otherwise, delete sentence.]

Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

[Include if the study involves more than one healthcare visit AND is greater than minimal risk; otherwise, delete sentence] During this study, we may find out something that might make you not want to stay in the study. If this happens, we will tell you as soon as possible.

[Include if the study has the potential for direct benefit or if the subjects are being paid; otherwise, delete sentence] We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

**Questions**

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact name at phone number. Also call if you need to report an injury while doing this research. [Include if the study is greater than minimal risk; otherwise, delete sentence] Contact name at phone number if there is no answer at that phone number or if you are calling after normal business hours.

You may also contact email Tamuk.irb@tamuk.edu. You will be talking to a member of the research compliance team at Texas A&M University-Kingsville. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

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| **SPECIAL DIRECTIONS** – delete this box from the submitted consent formYou are ready to select and edit the signature page, unless your study involves any of the following, in which case, copy the required language to the indicated sections. Delete this entire text box from the submitted version. 1. Genetic testing and/or collecting genetic information
	* In **What Will Happen in This Research Study**, describe:
	* Whether the research will or might include whole genome sequencing of biospecimens
	* Plans for future use of genetic samples and genetic data
	* The plans for return of pertinent and incidental findings (see 2. below), or a statement that no findings will be returned to subjects
	* In **Risks**, describe the psychological and socioeconomic risks related to generating personal genetic information (including risks to genetic relatives)
	* If results will be returned to subjects, include the following language in **Risks**:

There is a potential risk that your genetic information could be used to your disadvantage. For example, if genetic research findings suggest a serious health problem, that could be used to make it harder for you to get or keep a job or insurance. Several state laws and federal laws, particularly the Genetic Information Nondiscrimination Act (GINA), generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. These laws will generally protect you in the following ways: * + 1. Health insurance companies and group health plans may not request your genetic information that we get from this research.
		2. Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
	+ If data will be sent to an NIH database such as dbGaP, add the following language to **Confidentiality**:

Samples that are collected from you in this study will be analyzed to find out information about your genetics. Your genetics and health information, without your name or other data that could easily identify you, will be put in a database run by the National Institutes of Health (NIH). Other researchers can ask the NIH to get your information from the database. You should know that it is possible that your genetics information might be used to identify you or your family, though we believe it is not too likely that this will happen. Once your information is given to the NIH database, you can ask to have NIH stop sharing it, but NIH can’t take back information that was already shared. 1. Communication of pertinent and/or incidental findings to subjects and/or their physicians
	* In **What Will Happen in This Research Study**, describe:
* The anticipated findings that will be communicated and/or the criteria that will be used to determine which findings will be communicated if there may be unanticipated findings
* To whom and by whom the findings will be communicated, when, and how
* The reliability and limitations of the information provided by the findings
* Any further diagnosis or other actions may be required based on the findings, including their risks and costs to the subject (and to their relatives if applicable)
* Whether or not subjects can request not to have some, or all of the findings returned to themselves or their physicians, and if so, the categories of findings they can choose and the considerations relevant to making those choices
* The resources such as counseling available to subjects to help with receiving and interpreting findings

As applicable, edit and add the following when pertinent findings may be returned, either as a stand-alone paragraph or incorporated into the study-specific discussion:The research measurements we make are not necessarily the same as tests done by your doctor. We are collecting information on many people to answer our research questions. Not everyone doing the research tests is a doctor or a nurse. You or your doctor should not rely on research measurements to make any diagnosis, treatment, or health planning decisions. If you or your doctor decides that follow-up tests and treatments are necessary, then you or your insurance will be billed for the costs.As applicable, edit and add the following when incidental findings from imaging may be returned, either as a stand-alone paragraph or incorporated into the study-specific discussion:The imaging test you will have in this study is for research purposes only. However, we might see something that could be important to your health. If we do, we will ask you if you want us to explain what we noticed. If you would like, we will also tell your doctor. You or your doctor should not rely on research measurements to make any diagnosis, treatment, or health planning decisions. If you or your doctor decides that follow-up tests and treatments are necessary, then you or your insurance will be billed for the costs. As applicable, edit and add the following when no findings will be returned to subjects or their physicians:The tests we are doing in this study are for research purposes only. We will not tell you the results because explain the reason, such as it is not known if the results mean anything. 1. Repositories or other retention of samples or data
	* In **What Will Happen in This Research Study**, describe:
* How samples or data will be obtained
* What types of research will use the samples or data
* Whether genetic information will be included
* Plans for release of samples or data from the repository, including:
* What types of researchers may request release (from TAMUK, external universities, industry, government, etc.)
* Who will review requests for release to ensure the research is consistent with the aims of the repository
* What sample or data handling procedures will the researchers be required to agree to
* For the release of samples, what information will accompany the samples (demographics, diagnosis, etc.)
* If the study has the potential for direct benefit to the subject, a statement that agreeing to the retention of samples or data is optional and that the subject can agree to participate in the main study but not agree to having their samples retained
	+ In **Confidentiality**:
	+ Add: The repository has standard operating procedures to protect your confidentiality. A description of how specimens and/or data are stored and shared.
	+ Add the following bullet to the bulleted list of people who will receive identifiable samples/data:
* People who will get your data and your biological samples as we described in the section **What Will Happen in This Research Study**. These people are expected to protect your information and biological samples in the same way we protect it.
	+ In the **Signature** page, a witness is REQUIRED if limited- or non-readers are enrolled.
 |
| **SIGNATURE PAGES** – delete this box from the submitted consent formFive signature pages follow. Select and edit the one that applies to your study and delete the other four pages. 1. No written signatures (waiver of documentation of consent)
2. Signature of subject only
3. Signature of subject/ Legally Authorized Representative (LAR)
4. Signature of subject – limited- or non-readers excluded
5. Signature of subject/LAR – limited- or non-readers excluded

Limited- or non-readers**: should be included** unless there are specific reasons to exclude them. For research that is greater than minimal risk, to assure comprehension if limited- or non-readers are included, either an impartial witness must be present during the consent process or some other method will be used and documented, as described in the IRB application. Subjects physically unable to write: a subject who is physically unable to provide a signature on a consent form may provide consent or assent by requesting another person to sign in their presence. The person signing the form on behalf of the subject must be an adult and may not be the person conducting the consent discussion. The person signing the form on behalf of the subject must provide a statement to this effect on the page with their signature, such as “[Name] is unable to sign and has directed me to sign in their presence – [printed name of person signing].” If the study is likely to enroll subjects physically unable to write, the investigator may include a pre-printed statement to the signature page to be used in such circumstances.  |

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| **1. NO WRITTEN SIGNATURE** – delete this box from the submitted consent form |

By participating in this research, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

|  |
| --- |
| **Put this statement at the bottom of the final page FOR EXEMPT STUDIES ONLY--** delete this box from the submitted consent form |

**THIS RESEARCH PROJECT HAS BEEN REVIEWED BY THE TEXAS A&M UNIVERSITY—KINGSVILLE INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS.**

**If you have questions or concerns, those questions or concerns should be directed to the University IRB at****tamuk.irb@tamuk.edu****or (361)593-3344**

|  |
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| **2. SIGNATURE OF SUBJECT – NO LARs** – delete this box from the submitted consent form |

**Subject:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of subject

By signing this consent form, you are indicating that

* you have read this form (or it has been read to you)
* your questions have been answered to your satisfaction
* you voluntarily agree to participate in this research study
* you permit the use and release of information that may identify you as described [include if health information is obtained; otherwise, delete blue phrase] , including your health information.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of subject Date

**Researcher:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of person conducting consent discussion

I have personally explained the research into the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of person conducting consent discussion Date

[Include if a witness is the method that will be used to ensure comprehension by limited- and non-readers; otherwise, delete all text below] *To be completed by witness if researcher reads this form to the subject*

This consent form was read to and apparently understood by the subject in my presence.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of witness (a person not otherwise associated with the study)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of witness Date

|  |
| --- |
| **Put this statement at the bottom of the final page --** delete this box from the submitted consent form |

**THIS RESEARCH PROJECT HAS BEEN REVIEWED AND APPROVED BY THE TEXAS A&M UNIVERSITY—KINGSVILLE INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS.**

**If you have questions or concerns, those questions or concerns should be directed to the University IRB at****tamuk.irb@tamuk.edu****or (361)593-3344**

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|  |
| --- |
| **3. SIGNATURE WITH LARs** – edit depending on whether all signatures are by LARs or whether some signatures are by subjects – delete this box from the submitted consent form |

**Subject:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of subject

By signing this consent form, you are indicating that

* you have read this form (or it has been read to you)
* your questions have been answered to your satisfaction
* you voluntarily agree to participate in this research study
* you permit the use and release of information that may identify you as described [include if health information is obtained; otherwise, delete blue phrase] , including your health information.

[Include if some subjects may consent for themselves; otherwise, delete through *To be completed by LAR if subject does not personally sign*] *To be completed by subject if personally signing*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of subject Date

*To be completed by LAR if subject does not personally sign*

I am providing consent on behalf of the subject.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of Legally Authorized Representative (LAR) Relationship to Subject

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of Legally Authorized Representative Date

**Researcher:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of person conducting consent discussion

[Include if some subjects may consent for themselves; otherwise, delete through “*To be completed by researcher if subject* ***does not personally sign****”*] *To be completed by researcher if subject personally signs*

I have personally explained the research into the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of person conducting consent discussion Date

*To be completed by researcher if subject does not personally sign*

I have personally explained the research to the above-named subject’s Legally Authorized Representative and answered all questions. I believe that the Legally Authorized Representative understands what is involved in the study and freely agrees to have the subject participate. [Include if some subjects are capable of providing assent; otherwise delete sentence and two checkboxes – retain signature of researcher] I consider that the above-named subject (check one):

🞏 is capable of understanding what is involved in the study and freely agrees to participate.

🞏 is not capable of understanding what is involved in the study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of person conducting consent discussion Date

[Include if a witness is the method that will be used to ensure comprehension by limited- and non-readers; otherwise, delete all text below] *To be completed by witness if researcher reads this form to the subject/LAR*

This consent form was read to and apparently understood by the subject/Legally Authorized Representative in my presence.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of witness (a person not otherwise associated with the study)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of witness Date

|  |
| --- |
| **Put this statement at the bottom of the final page --** delete this box from submitted consent form |

**THIS RESEARCH PROJECT HAS BEEN REVIEWED AND APPROVED BY THE TEXAS A&M UNIVERSITY—KINGSVILLE INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS.**

**If you have questions or concerns, those questions or concerns should be directed to the University IRB at****tamuk.irb@tamuk.edu****or (361)593-3344**

|  |
| --- |
| **4. SIGNATURE OF SUBJECT – NO LARs – LIMITED- AND NON-READERS EXCLUDED** – delete this box from submitted consent form |

**Subject:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of subject

By signing this consent form, you are indicating that

* you have read this form
* your questions have been answered to your satisfaction
* you voluntarily agree to participate in this research study
* you permit the use and release of information that may identify you as described [include if health information is obtained; otherwise, delete blue phrase] , including your health information.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of subject Date

**Researcher:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject (who has read this consent form) and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of person conducting consent discussion Date

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|  |
| --- |
| **5. SIGNATURE WITH LARs – LIMITED- AND NON-READERS EXCLUDED** – edit depending on whether all signatures are by LARs or whether some signatures are by subjects – delete this box from submitted consent form |

**Subject:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of subject

By signing this consent form, you are indicating that

* you have read this form
* your questions have been answered to your satisfaction
* you voluntarily agree to participate in this research study
* you permit the use and release of information that may identify you as described [include if health information is obtained; otherwise, delete blue phrase] , including your health information.

[Include if some subjects may consent for themselves; otherwise, delete through “*To be completed by LAR if subject* ***does not personally sign****”*] *To be completed by subject if personally signing*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of subject Date

*To be completed by LAR if subject does not personally sign*

I am providing consent on behalf of the subject.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of Legally Authorized Representative (LAR) Relationship to Subject

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of Legally Authorized Representative Date

**Researcher:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of person conducting consent discussion

[Include if some subjects may consent for themselves; otherwise, delete through “*To be completed by researcher if subject* ***does not personally sign****”*] *To be completed by researcher if subject personally signs*

I have personally explained the research to the above-named subject (who has read this consent form) and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of person conducting consent discussion Date

*To be completed by researcher if subject does not personally sign*

I have personally explained the research to the above-named subject’s Legally Authorized Representative (who has read this consent form) and answered all questions. I believe that the Legally Authorized Representative understands what is involved in the study and freely agrees to have the subject participate. [Include if some subjects are capable of providing assent; otherwise delete sentence and two checkboxes – retain signature of researcher] I consider that the above-named subject (check one):

🞏 is capable of understanding what is involved in the study and freely agrees to participate.

🞏 is not capable of understanding what is involved in the study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of person conducting consent discussion Date

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